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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Before the Patent Office Board of Appeals

APPLICANT: Philip Connolly

G.A.U: 1761

SERIAL NO.: 10/045,803

EXAMINER: K. D. Hendricks

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St. Louis, Missouri

FOR: Method of Enhancing Absorption and
Utilization of Protein

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D.N.: 7287

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BRIEF FOR APPLICANT
RESUBMITTED

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Citation of Cases and Statutes

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Cases:

<i>KSR Int'l Co. v. Teleflex, Inc.</i> , 82 U.S.P.Q. 2d 1385 (U.S. 2007)	
.....	9, 10, 13

Statutes:

35 U.S.C. § 102 (b).....	6, 7, 8, 9
35 U.S.C. § 102.(e).....	6, 11
35 U.S.C. § 103 (a).....	6, 7, 9, 11

I. Real Parties in Interest

The parties in interest in this particular application include the inventor, Philip Connolly, and the Company to which he has assigned this application, Commercial Proteins Corporation.

II. Related Appeals and Interferences

There are no related appeals, or interference proceedings, pertaining to the subject matter of this patent application.

III. Status of Claims

The examiner issued a final rejection on October 7, 2003. Applicant filed an Amendment B, after final rejection, on or about October 30, 2003. On December 2, 2003, the examiner issued an office action stating that the Amendment B failed to place the application into condition for allowance. Thus, at that time, for purposes of appeal, the claims in the case were 1, 2, 3, 7, 8, and 10.

Applicant has previously filed a Notice of Appeal on February 5, 2004. At this time, the claims in this application include Claims 1, 2, 3, 7, 8, and 10. These are the claims upon which the Appeal Brief is filed.

IV. Status of Amendments

All of applicant's amendments subsequent to the final rejection apparently have been entered by the examiner, and therefore, the claims upon appeal are 1, 2, 3, 7, 8, and 10, as set forth in the Amendment B. These claims are set forth in the Appendix.

More specifically, applicant filed an Amendment A on July 16, 2003. That Amendment was rejected, for enablement, informalities, and obviousness on references to Meister et al. Applicant submitted an Amendment B on October 30, 2003 overcoming the informalities and attempting to render the claims more definite and non-obvious, but the examiner continued his rejections.

The Notice of Appeal was filed, and the brief was submitted accordingly.

V. Summary of the Claimed Subject Matter

This invention, specification page 5 line 1, uses a milk protein concentrate page 4 lines 12-16, or other related proteins, which are fortified or cultured with a probiotic bacteria or combination of several probiotic bacteria page 11 line 4. The fortified milk protein concentrate improves the overall digestive health of the consumer while providing the basic building blocks for muscle tissue page 10 line 2, such as amino acids page 9 lines 21-25 and page 10 line 4. The invention enhances absorption and utilization of protein from the gastrointestinal tract from a high protein diet page 10 line 5. Consuming the invention improves health, and fosters a higher degree of anabolism over catabolism page 2 lines 11-16 and page 10 line 1. In usage of the invention, the serious athlete gains muscle while consumers will increase their overall strength and resistance to disease.

The invention also relates to an improved milk protein concentrate and its method of production. The invention provides for the oral administration page 12 line 8 of a milk protein concentrate, i.e., the milk protein of skim milk concentrated to a higher percentage of protein by removal of undesired constituents. The protein concentrates are combined with probiotic bacteria including *bifido* bacterium page 7 lines 6-11 and page 8 lines 22-23, *Lactobacillus plantarum* page 8 line 17, *Lactobacillus helveticus* page 11 lines 7-8, *Lactobacillus paracasei* page 12 line 1, *Lactobacillus bulgaricus* page 8 line 18, *Streptococcus thermophilus* page 8 line 18, and other yogurt culture bacteria. These bacteria, the most important intestinal bacteria for humans, are classified as probiotic because of their benefit to living organisms.

The invention is also a method of production and administration of an improved performance milk protein concentrate that maximizes the efficient production of protein that can grow healthy muscle tissue page 10 lines 2-6. The invention makes protein absorption more efficient when metabolized by the body, between approximately 1.5 to 4.0 grams of protein consumed per kilogram of body weight per day page 6 lines 21-25.

VI. Grounds of Rejection

The issue concerned is whether Claims 1, 2, 7, and 10 are anticipated under §102(b), or in the alternative, rendered obvious under §103(a), over the patent to Bohren.

A second issue is whether Claim 1 remains rejected under §102(b) as anticipated, or in the alternative obvious under §103(a), over any of the patents to Kronberg, Jameson, Nielsen, or Kosikowski.

A third issue is whether Claims 1-3, 7-8, and 10 are rejected under §102(e) as anticipated, or in the alternative as obvious under §103(a) over Meister.

There appears to be three groups of claims in this appeal, one group is Claims 1, 2, and 3. The second group is claims 7 and 8. And, the third group is claim 10.

Applicant bases its appeal upon three groups of claims as set forth above. It is applicant's position that all of the claims do not stand or fall together. Within the groups, the claims may stand or fall together, but not all of the claims collectively.

Claims 1, 2, and 3, comprising a first group of claims, will stand or fall together.

Claims 7 and 8 are a second group, and will stand or fall together.

And, the third group, claim 10, stands or falls alone.

VII. Argument

Rejection of Claims 1, 2, 7, 10 under 35 U.S.C. §102(b) or in the alternative 35 U.S.C. §103(a) over U.S. Pat. No. 3,793,465 to Bohren:

Regarding anticipation, Claims 1, 7, and 10 define a method of enhancing protein absorption by humans during digestion of more protein than regularly consumed. Consuming a concentrate of milk protein and probiotic bacteria, a person augments the protein usually eaten with meals. Claims 1, 7, 10 specify a range of total protein consumed daily, including regular protein from meals, and the present invention. The claimed range provides one skilled in the art a range of total protein consumed so that the practitioner adjusts each individual's protein consumption to fall within the claimed range.

A trained practitioner, such as a physician, dietician, and the like, interviews an individual about their diet and meals. With diet information and food value tables, a practitioner determines the individual's starting daily protein intake. The practitioner then subtracts the starting daily protein intake from the claimed range to provide a range of the present invention to administer. The range of actual concentrate permits the practitioner to adjust the consumption of the present invention to meet the needs of the individual and still fall within the claimed range of total daily protein consumption.

Claim 1 defines a method of promoting protein absorption and utilization from the gastro intestinal track of an athlete, such as a body builder, and comprising the oral administration of a combination of milk protein concentrates and probiotic bacteria. Claim 2 defines the group from which the probiotic bacteria are selected. Claim 7 defines the further method of promoting protein utilization, wherein the probiotic bacteria are selected from bifido bacteria and other lacto related organisms. And, the composition is administered in an amount of the combination to increase the athlete's total daily consumption of protein to between about 1.5 grams and approximately 4.0 grams of protein per kilogram of body weight per day. Claim 10 defines the method of promoting the higher ratio of anabolism as compared to catabolism, for promoting muscle

tissue growth, for amino acid production in the intestines of the athlete, and for utilization of protein consumed by the athlete.

Though Bohren may disclose the preparation of *Lactobacillus bulgaricus* and *Streptococcus thermophilus* within his powder formed composition, that does not equate to the usage of this type of bacteria at the specific consumption levels of the present invention, at a specific gram weight per kilogram of body weight per day. Furthermore, Bohren does not define the amount of organisms within the range per gram of milk protein concentrate, as suggested in claim 1. Hence, it is questioned as to whether the method of claim 1, and its dependant claim 2, in addition to the method of claims 7 and 10 are anticipated by Bohren under §102 (b).

Regarding obviousness, Claims 1, 7, and 10 define a method of enhancing protein absorption by humans during digestion from a concentrate of milk protein and probiotic bacteria. In one embodiment, the present invention filters liquid skim milk to a high concentration of protein, adds probiotic bacteria to the concentrated liquid, and then the concentrated liquid is then spray dried. In an alternate embodiment, the present invention has a high protein milk powder mixed with a powder containing the probiotic bacteria. The inoculated concentrated powder is then mixed until homogeneous. In both embodiments, a human consumes the present invention as a liquid reaping the benefits from more efficient protein digestion encouraged by the probiotic bacteria. Two part protein concentrates appear in the Bohren patent as a two part acidic milk powder having an acid compound coated in an edible fat with an emulsifier. This is distinct from the two parts combined in a concentrate independent of their acidity or coating characteristics as in the present invention. Claims 1, 7, and 10 clearly describe a milk concentrate with a range of protein content and a range of probiotic bacteria concentration. To the contrary, Bohren emphasizes pH and acid coating in its claimed structure.

In addition, the Bohren patent does not appear to define or suggest the usage of its acidified milk product in a powder form for promoting protein absorption and utilization from the gastro intestinal track of an athlete, in the

amounts as specified in these claims. And, since Bohren does not suggest the usage of a milk protein concentrate, supplemented by the identified bacteria, in these amounts, it is argued that Applicant's claimed method, likewise, is not rendered obvious from this particular prior art patent.

The examiner's attention is directed to the case of *KSR Int'l Co. v. Teleflex, Inc.*, 82 U.S.P.Q. 2d 1385 (U.S. 2007). The court discussed that reasons, such as design incentives and market forces, can prompt a person to make a predictable variation upon existing products. *Id.* The reason must prompt a person of ordinary skill to combine the elements from the prior art as done in the claimed invention for it to be obvious. *Id.* at 1396. Here though, the prior art is directed towards pH level of the powder and coating of the powder, different usages of ingredients, or different methods of their production, such as for drying a probiotic composition which differs from the present invention of a specific mixture of a probiotic composition, with a milk protein concentrate, and then administering that composition in a precise amount based upon the kilogram of body weight of the athlete, per day.

Rejection of Claim 1 under 35 U.S.C. §102(b) or in the alternative 35 U.S.C. §103(a) over U.S. Pat. Nos. 2,127,524 to Kronberg, 5,356,640 to Jameson, 5,232,720 to Nielsen, or 5,098,721 to Kosikowski:

Regarding anticipation, Claim 1 defines a method of enhancing protein absorption by humans during digestion of more protein than regularly consumed. Consuming a concentrate of milk protein and probiotic bacteria, a human augments their protein eaten with meals. Claim 1 specifies a range of total protein consumed daily, including from meals and the present invention. The claimed range provides one skilled in the art a range of total protein consumed where the practitioner can adjust each individual's protein consumption within the claimed range.

A trained practitioner, such as a physician, dietician, and the like, interviews an individual about their diet. With diet information and food value tables, a practitioner determines the individual's starting daily protein intake. The

practitioner then subtracts the starting daily protein intake from the claimed range to provide a range of the present invention to administer. The range of actual concentrate permits the practitioner to adjust the present invention for consumption to meet the needs of the individual within the claimed range of total daily protein consumption.

Then on the obviousness issue, Claim 1 defines a two part milk concentrate having a range of protein and a range of probiotic bacteria in either liquid or powder form. The range of protein makes up the major part and the probiotic bacteria make up the minor part of the concentrate. The concentrate provides protein for delivery to a human and probiotic bacteria to accelerate that delivery. A milk powder having a major part and a minor part appears in Kronberg. The minor part is treated by bacteria to convert sugar in skim milk thus, acidifying the minor part. The major part remains the same or has sugar added. Combined and dried, the major part and the minor part resist clumping in storage and other bacteria upon reconstitution. This is distinct from powdered bacteria added to protein in a concentrate to aid absorption of protein by a human upon reconstitution in water. Claim 1 describes with clarity a two part concentrate of bacteria and protein but does not claim bacteria that inverts sugar into an acidic solution.

None of the four references cited as a basis for anticipation, suggest Applicant's claimed method. And in particular, none of the references provide an incentive or follow a market force for providing an athlete with a sufficient amount of the claimed combination of milk protein concentrates, and probiotic bacteria, to increase the athlete's total daily consumption of protein to between approximately 1.5 grams and 4.0 grams of protein per kilogram of body weight per day. The prior art does not address or suggest the protein range within the probiotic milk protein concentrate.

As before, the examiner's attention is directed to the case of *KSR Int'l Co. v. Teleflex, Inc.*, 82 U.S.P.Q. 2d 1385 (U.S. 2007). The court discussed that reasons, such as design incentives and market forces, can prompt a person to make a predictable variation upon existing products. *Id.* The reason must prompt

a person of ordinary skill to combine the elements from the prior art as done in the claimed invention for it to be obvious. *Id* at 1396. In other words, the prior art is directed towards acidifying skim milk using a two part formulation, different usages of ingredients, or different methods of their production, such as for drying a probiotic composition which differs from the present invention of a specific mixture of a probiotic composition, with a milk protein concentrate, and then administering that composition in a precise amount based upon the kilogram of body weight of the athlete, per day.

Rejection of Claims 1, 2, 3, 7, 8, 10 under 35 U.S.C. §102(e) or in the alternative 35 U.S.C. §103(a) over U.S. Pat. No. 6,200,609 to Meister:

Regarding anticipation, Claims 1, 2, 3, 7, 8, 10 define a method of enhancing protein absorption by humans during digestion of more protein than regularly consumed. Consuming a concentrate of milk protein and probiotic bacteria, a human augments their protein eaten with meals. Claim 1 specifies a range of total protein consumed daily, from meals and from the present invention. The claimed range provides one skilled in the art a range of total protein consumed that the practitioner adjusts for each individual's protein consumption.

A trained practitioner, such as a physician, dietician, and the like, interviews an individual about their diet. With diet information and food value tables, a practitioner determines the individual's starting daily protein intake. The practitioner then subtracts the starting daily protein intake from the claimed range to provide a range of the present invention to deliver to the athlete. The range of actual concentrate permits the practitioner to adjust the present invention for consumption to meet the needs of the individual and still fall within the claimed range of total daily protein consumption.

Claims 1, 7, and 10 establish either a liquid or powder concentrate of milk having ranges of protein and probiotic bacteria ingredients. For the liquid concentrate form, filtered skim milk has probiotic bacteria added. The bacteria laden skim milk is then spray dried under gentle low heat into a powder. To form

the powder concentrate of the invention, the powdered milk has powdered probiotic bacteria added and is then mixed mechanically to distribute the bacteria homogeneously in the concentrate. A spray dried milk powder occurs in Meister. Meister claims a spray of food and a spray of bacteria combined and subsequently dried in at least a 100°C environment with mixing air to drop the temperature so some of the bacteria survive. This is distinct from powdered bacteria added to liquid or powdered milk and then spray dried or mechanically mixed, respectively, in a moderate temperature environment. Claims 1, 7, and 10 clearly describe combining protein and probiotic bacteria prior to drying or mixing.

Then on the obviousness issue, the particular method of enhancing absorption and utilization of protein of this invention, as now claimed herein, is not so suggested by the prior art. While the examiner states that Meister co-sprays two components to form a combined powder, Meister shows nothing more than two liquids, one containing bacteria, sprayed into a chamber and air dried at high temperature, no different than what is shown in Bohren and Kronberg, and therefore, does not provide an incentive or follow a market force with respect to a desired total daily protein consumption utilizing bacteria. Bohren discloses an acidic compound coated in fat, solid at room temperature, and Kronberg reveals a two part milk powder with one part being acidic and both do not suggest how Meister could be modified, to become the applicant's claimed invention.

Meister is primarily concerned with the process for obtaining and utilizing a dehydrated food composition that contains a probiotic lactic acid bacteria, rather than any method for usage of this type of composition or its absorption within an athlete on a high protein diet. Meister goes into detail in describing the method to carry out his process, where the culture of one or more species of probiotic lactic acid bacteria is prepared. Though Meister refers to a number of bacteria, Meister primarily shows how to culture lactic acid bacteria that preferably contains at least 10^7 live cell colonies per gram, where apparently the

composition is spray dried, to reduce its water content, to attain the dehydrated product. This is not the Applicant's invention.

On the other hand, Applicant provides a method of promoting protein utilization and absorption in the athlete, on a high protein diet, through an oral administration of a combination of the milk protein concentrate and the probiotic bacteria, where the administered amount of the present invention increases the athlete's total daily consumption protein to between approximately 1.5 grams and approximately 4.0 grams of protein per kilogram of body weight per day. The patent to Meister does not suggest this type of method or invention.

As before, the examiner's attention is directed to the case of *KSR Int'l Co. v. Teleflex, Inc.*, 82 U.S.P.Q. 2d 1385 (U.S. 2007). The court discussed that reasons, such as design incentives and market forces, can prompt a person to make a predictable variation upon existing products. *Id.* The reason must prompt a person of ordinary skill to combine the elements from the prior art as done in the claimed invention for it to be obvious. *Id.* at 1396. In other words, the prior art is directed towards lactic acid bacteria exceeding the 10^7 live cells per colony following drying, different usages of ingredients, or different methods of their production, such as for drying a probiotic composition which differs from the present invention of a specific mixture of a probiotic composition, with a milk protein concentrate, and then administering that composition in a precise amount based upon the kilogram of body weight of the athlete, per day.

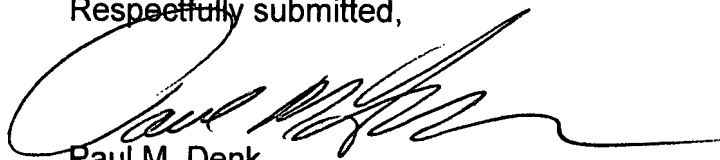
VIII. Conclusion

It is submitted that patentable subject matter is set forth in the remaining claims of this application. It is believed that the claim subject matter enables one skilled in the art to determine definitively a range of protein amount administered, not rendered obvious, to one of ordinary skilled in the art, nor does any combination of the prior art as cited by the examiner, provide a market force or design incentive to deduce the Applicant's invention. Hence, it is believed that patentable subject matter is set forth in the claims remaining in this application.

The Board's review of this matter would be appreciated.

If any additional charges are due, please debit our deposit account #040731.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Paul M. Denk', with a long horizontal flourish extending to the right.

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APPENDIX (Claims)

1. A method of promoting protein absorption and utilization from the gastrointestinal tract of a subject comprising the oral administration of a combination of milk protein concentrates and probiotic bacteria in an amount sufficient to increase the subject's total daily consumption of protein to between approximately 1.5 grams and approximately 4.0 grams of protein per kilogram of body weight per day; the milk protein concentrate having a protein content of about 65% to about 90% and there being about 100,000 to about 50,000,000 probiotic bacteria organisms per gram of milk protein concentrate.

2. The method of claim 1 wherein the probiotic bacteria is selected from the group consisting of *bifido* bacteria, *Lactobacillus plantarum*, *Lactobacillus helveticus*, *Lactobacillus paracasei*, *Lactobacillus bulgaricus*, *Streptococcus thermophilus* and combinations thereof.

3. The method of claim 1 wherein the probiotic bacteria consists of *Bifidobacterium longum* combined with *Lactobacillus bulgaricus* and *Streptococcus thermophilus*.

7. A method of promoting protein utilization and absorption in a subject on a high protein diet comprising the oral administration of combination of milk protein concentrates and probiotic bacteria, the probiotic bacteria being selected from the group consisting of *bifido* bacteria, *Lactobacillus plantarum*, *Lactobacillus helveticus*, *Lactobacillus paracasei*, *Lactobacillus bulgaricus*, *Streptococcus thermophilus* and combinations thereof; the subject being administered an amount of the combination sufficient to increase the subject's total daily consumption of protein to between approximately 1.5 grams and approximately 4.0 grams of protein per kilogram of body weight per day.

8. The method of claim 7 wherein the probiotic bacteria consists of *Bifidobacterium longum* combined with *Lactobacillus bulgaricus*, *Streptococcus thermophilus*, or combinations thereof.

10. A method of promoting higher ratio of anabolism as compared to catabolism, promoting muscle tissue growth, promoting amino acid production in the intestinal tract in an athlete and promoting the utilization of protein consumed

by the athlete, the method comprising the consumption by the athlete of a combination of milk protein concentrates and probiotic bacteria, the probiotic bacteria being selected from the group consisting of *bifido* bacteria, *Lactobacillus plantarum*, *Lactobacillus helveticus*, *Lactobacillus paracasei*, *Lactobacillus bulgaricus*, *Streptococcus thermophilus* and combinations thereof; the athlete consuming an amount of the combination sufficient to increase the athlete's total daily consumption of protein to between approximately 1.5 grams and approximately 4.0 grams of protein per kilogram of body weight per day.

APPENDIX (Evidence)

The Applicant has not submitted evidence pursuant to 37 CFR §§ 1.130, 1.131, and 1.132 nor other evidence and thus, there is no related evidence provided in this appendix.

APPENDIX (Related Proceedings)

No other related appeals have resulted in a decision by a court or the Board bearing upon this application and appeal, and thus, there are no related decisions provided in this appendix.